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|-------------------------------|------------------------|---------------------|--|
| Notice of Allowability | Application No. | Applicant(s) | |
| | 09/938,077 | LOK, SI | |
| | Examiner | Art Unit | |
| | Kenneth R Horlick | 1637 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the response filed 08/21/03 and interview of 11/06/03.
 2. ☒ The allowed claim(s) is/are 1-11 and 15-20 (final claims 1-17).
 3. ☒ The drawings filed on 23 August 2001 are accepted by the Examiner.
 4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
- * Certified copies not received: _____.
5. ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
 - (a) ☐ The translation of the foreign language provisional application has been received.
 6. ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. **THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

7. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
8. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No. _____.
 - (b) ☐ including changes required by the proposed drawing correction filed _____, which has been approved by the Examiner.
 - (c) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No. _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the margin according to 37 CFR 1.121(d).

9. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|--|--|
| 1 <input type="checkbox"/> Notice of References Cited (PTO-892) | 5 <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 2 <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6 <input checked="" type="checkbox"/> Interview Summary (PTO-413), Paper No. _____ |
| 3 <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No. _____ | 7 <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4 <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit of Biological Material | 8 <input type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9 <input type="checkbox"/> Other _____ |

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Michelle Johnson on 11/06/03.

The application has been amended as follows:


EXAMINER'S AMENDMENT

- Cancel claims 21-26 without prejudice.

2. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kenneth R Horlick whose telephone number is 703-308-3905. The examiner can normally be reached on Monday-Thursday 6:30AM-5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 703-308-1119. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


Kenneth R Horlick
Primary Examiner
Art Unit 1637

11/10/03

ALLOWED CLAIMS/ TJ

Claim 1 (currently amended): A method for producing a nucleic acid molecule that comprises a continuous nucleotide sequence capable of being transcribed and translated to produce a protein of interest, the nucleic acid molecule derived from noncontiguous nucleotide sequences, comprising:

(a) amplifying at least two nucleotide sequences from a single nucleic acid molecule template using primer pairs to produce double-stranded amplified products, wherein the amplified nucleotide sequences reside noncontiguously in the nucleic acid molecule template, wherein each primer of a primer pair comprises an continuous uninterrupted recognition sequence for a class IIS restriction endonuclease which is located near the 5'-end of the primer and a portion of an amino acid coding sequence, such that cleavage of the amplified products with the class IIS restriction endonuclease yields at least two nucleic acid molecule fragments with cohesive ends that, when ligated to each other, produce a continuous nucleotide sequence capable of being transcribed and translated to produce a protein of interest,

(b) cleaving amplified products with the class IIS restriction endonuclease to produce nucleic acid molecule fragments, and

(c) ligating cleaved nucleic acid molecule fragments to produce a nucleic acid molecule comprising the continuous nucleotide sequence capable of being transcribed and translated to produce a protein of interest.

Claim 2 (previously presented): A method for producing a nucleic acid molecule that comprises a continuous nucleotide sequence capable of being transcribed and translated to produce a protein of interest, the nucleic acid molecule derived from noncontiguous nucleotide sequences, comprising:

(a) amplifying at least two nucleotide sequences from at least two nucleic acid molecule templates using primer pairs to produce double-stranded amplified products, wherein ~~each~~ at least one primer of a primer pair comprises an continuous uninterrupted recognition sequence for a class IIS restriction endonuclease which is located near the 5'-end of the primer and a portion of an amino acid coding sequence, such that cleavage of the amplified products with the class IIS restriction endonuclease yields at least two nucleic acid molecule fragments with cohesive ends that, when ligated to each other, produce a continuous nucleotide sequence capable of being transcribed and translated to produce a protein of interest,

(b) cleaving amplified products with the class IIS restriction endonuclease to produce nucleic acid molecule fragments, and

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(c) ligating cleaved nucleic acid molecule fragments to produce a nucleic acid molecule comprising the continuous nucleotide sequence capable of being transcribed and translated to produce a protein of interest.

Claim 3 (currently amended): The method of claim 1, wherein the class IIS restriction endonuclease recognizes a five-base ~~continuous~~ uninterrupted recognition sequence.

Claim 4 (previously presented): The method of claim 3, wherein the class IIS restriction endonuclease is selected from the group consisting of *AccI*, *Alw26I*, *AlwI*, *AsuHPI*, *BbvI*, *BceFI*, *BinI*, *BseGI*, *BseMII*, *BseXI*, *BspPI*, *BsmAI*, *Bst7II*, *BstF5I*, *FauI*, *FokI*, *HgaI*, *HphI*, *MboII*, *PleI*, *SfaNI*, and *TspRI*.

Claim 5 (currently amended): The method of claim 1, wherein the class IIS restriction endonuclease recognizes a six-base ~~continuous~~ uninterrupted recognition sequence.

Claim 6 (previously presented): The method of claim 5, wherein the class IIS restriction endonuclease is selected from the group consisting of *AceIII*, *BbsI*, *BbvII*, *Bce83I*, *BciVI*, *BfiI*, *BfuI*, *BmrI*, *BpiI*, *Bpml*, *BpuAI*, *BsaI*, *Bse3DI*, *BseRI*, *BsgI*, *BsmBI*, *BsmFI*, *BspMI*, *BsrDI*, *Bsu6I*, *Eam1104I*, *EarI*, *Eco31I*, *Eco57I*, *Esp3I*, *FauI*, *GsuI*, *Ksp632I*, *MmeI*, *RleAI*, *TaqII*, and *Tth111II*.

Claim 7 (currently amended): The method of claim 1, wherein the class IIS restriction endonuclease recognizes a seven-base ~~continuous~~ uninterrupted recognition sequence.

Claim 8 (previously presented): The method of claim 7, wherein the class IIS restriction endonuclease is *SapI*.

Claim 9 (previously presented): The method of claim 1, wherein the nucleic acid molecule template is selected from the group consisting of genomic DNA, cDNA, vector DNA, and a chemically-synthesized nucleic acid molecule.

Claim 10 (previously presented): The method of claim 2, wherein at least one nucleic acid molecule template is selected from the group consisting of genomic DNA, cDNA, vector DNA, and a chemically-synthesized nucleic acid molecule.

Claim 11 (previously presented): The method of claim 1, wherein each of the amplified products comprises at least a portion of an exon.

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Claim 15 (previously presented): The method of claim 1, wherein at least one of the amplified products comprises at least a portion of an exon, and at least one of the amplified products comprises a nucleotide sequence capable of controlling gene expression.

Claim 16 (previously presented): The method of claim 1, ~~wherein the continuous nucleotide sequence of interest encodes an amino acid sequence, and~~ wherein each of the amplified products comprises an exon.

Claim 17 (previously presented): The method of claim 16, wherein one primer of each primer pair is partially complementary to the antisense strand of the 5' end of an exon, and wherein the other primer of each primer pair is partially complementary to the sense strand of the 3'-end of the exon.

Claim 18 (previously presented): The method of claim 1, wherein at least one of the amplified products comprises at least one mutation of the nucleotide sequence, which resides in the corresponding nucleic acid molecule template.

Claim 19 (previously presented): The method of claim 18, wherein at least one mutation resides in an amino acid encoding sequence.

Claim 20 (previously presented): The method of claim 1, wherein the act of amplification is performed using a polymerase chain reaction.